



ISSN Print: 2394-7489
ISSN Online: 2394-7497
IJADS 2015; 1(4): 136-140
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www.oraljournal.com
Received: 13-08-2015
Accepted: 14-09-2015

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To compare the effect of Triphala gel formulation and Cinnamomum gel formulation on gingivitis - A clinical study

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Abstract

Periodontal disease is characterized by inflammation and/or destruction of supporting tissue of the teeth. Bacterial plaque is the primary etiological agent in periodontal diseases. In addition to mechanical plaque removal measures, chemical plaque control measures have also been advocated that can be used as an adjunct to mechanical measures, which together can reduce plaque associated gingivitis. A clinical trial was conducted to compare and evaluate the effectiveness of two commercially available gum gels containing Triphala and Cinnamomum in the reduction of plaque and gingival inflammation in subjects with gingivitis. Total 60 subjects were selected from those diagnosed as having chronic gingivitis between 25 to 40 years were included in the study, out of which 20 (group I) were control group who received scaling only, 20 subjects (group II) received scaling and herbashine herbal gum paint® application (uniroyal biotech) and 20 subjects (group III) received scaling and Hi-ora GA® gum gel application (himalaya herbal health care) and The gingival index described by Loe H. and Silness P. and plaque index described by (Tureskey *et al.* Modification of Quigley Hein Index) were measured and recorded at baseline, 2 weeks, 4weeks and 6weeks interval. All the values at each time were recorded on appropriate forms during assessment. It was concluded from the present study that both the gel have been found to be effective in improving gingival status and resulted in significant improvement in clinical parameters, HiOra-GA® gum gel was found to be more effective than Herbashine Herbal Gum Paint®

Keywords: Gingivitis, Plaque, Antiplaque agent

1. Introduction

Periodontal disease is characterized by inflammation and/or destruction of supporting tissue of the teeth. Bacterial plaque is the primary etiological agent in periodontal diseases. Experimental gingivitis studies have proved the role of plaque in the etiology of periodontal infections and demonstrated the direct relationship between plaque levels and the development of gingivitis [1]. Mechanical periodontal therapy, like scaling is the first recommended step in the management of gingivitis and periodontitis and are an indispensable phase of periodontal therapy, but there are factors such as accessibility or presence of plaque retentive areas that can limit instrumentation. Therefore, in addition to mechanical plaque removal measures, chemical plaque control measures have also been advocated that can be used as an adjunct to mechanical measures, which together can reduce plaque associated gingivitis [2, 3]. Several chemical plaque control agents have been evaluated for their effectiveness on supragingival plaque including bis-biguanides, essential oils, enzymes, and even herbal extract. Some of these substances have been associated with various adverse effects incapacitating their long term use, so new formulation of equal efficacy and fewer side effects are required to be evaluated. Herbal formulations can provide an option for safe and long-term use [4, 5]. Triphala Curna (TC) is one of the well-known powdered preparations in Indian system of health care, Ayurveda since ancient time [6]. Triphala Curna comprises of a coarse powder made out of three myrobalans, *Embllica officinalis* Gaertn (Amla), *Terminalia chebula* Retz. (Haritaki) and *Terminalia belerica* Roxb. (Bibhitaki) blended in equal proportion [7, 8]. TC is used to promote immunity [9]. TC shows immunomodulatory properties [10] and helps in improving the body's defense system and has antimutagenic, radio protecting and antioxidant activity [11-17].

Cinnamomum camphora of the family Lauraceae contains volatile chemical compounds, and is used as antiseptic and tanning agents. It precipitates proteins but does not penetrate cells thereby affecting only the superficial layer making it stronger and preventing exudation [18]. Clove has essential oils, containing about 50% carvone, rosmarinic acid and has analgesic, antifungal, antioxidant, aromatic and astringent properties hence used as an anodyne [19]. Ajwain (*Trachyspermum ammi*) is an annual herbaceous plant belonging to the highly valued medicinally important family, Apiaceae. Ajwain seeds revealed to possess antiseptic, anesthetic, antimicrobial, antiviral, nematocidal, antiulcer, antihypertensive, antitussive, bronchodilatory, antiplatelet and hepatoprotective as well as antihyperlipidemic effects [20].

Melia azedarach has organic molecules such as terpenoids, flavonoids, steroids, acids, anthraquinones, alkaloids, saponins, tannins and has antioxidative, analgesic, anti-inflammatory, insecticidal, rodenticidal, antidiarrhoeal, deobstruent, diuretic, antidiabetic, cathartic, emetic, antirheumatic and antihypertensive properties [21]. *Mentha spicata* essential oil contains 44 compounds. The major compound was carvone, Limonene, 1, 8-cineol, germacrene-D, β -caryophyllene, β -bourbonene, α -terpineol. It has following properties like analgesic, antifungal, antioxidant, aromatic, astringent, carminative, diuretic, expectorant, febrifuge, insect repellent and stimulant [22]. Clinical trials by Prakash and Shelke *et al.* have shown the use of Triphala mouthwash in dentistry especially because of its antimicrobial and anti-oxidant effect [23].

Clinical trials for assessment of safety and efficacy of these herbal remedies are in its infant stage hence, the present study was planned to evaluate and compare the efficacy of commercially available Triphala gel formulation and Cinnamomum gel formulation as a topical application and gum massage, in the reduction of plaque and gingival inflammation in subjects with gingivitis.

2. Materials and Method

A randomized, controlled, full mouth clinical study was conducted, and the inclusion criteria for patient selection were systemically healthy patients between 25 – 40 years, presence of minimum of 20 teeth in the dentition, patients with bleeding on probing present and clinically Probing depth less than 4mm. Exclusion criteria were subjects taking antibiotics in the past 3 months, pregnant women and lactating mothers, patients with systemic disease and medically compromising condition, smokers and patient who have received any periodontal therapy in the past 6 months.

60 Subjects were selected having chronic gingivitis (based on the 1999 Classification of Periodontal Diseases and Conditions). The patients were divided into 3 groups randomly to receive various treatment options.

Group I - Scaling only (Control group) (n= 20)

Group II - Scaling + Herbashine Herbal Gum Paint® (Uniroyal biotech) (n=20)

Group III - Scaling + HiOra-GA® gum gel (Himalaya herbal health care) (n= 20)

2.1 Treatment Procedures

Scaling was performed and modified Bass method of brushing technique was demonstrated to all the selected subjects. They

were educated and motivated to follow the same brushing technique during the course of the study. Subjects were instructed to apply a pea-sized amount of formulation gently by finger or soft brush on the gingiva and massage twice daily and to leave it for five minutes before rinsing. Subjects were also asked to refrain from all other unassigned forms of oral hygiene aids, including dental floss, chewing gum or oral rinse during the study. Subjects were assessed for gingivitis using the Gingival index (GI) (Loe and Silness) and for plaque, using the Plaque index (PI) (Tureskey *et al.* modification of Quigley Hein Index) in the same dental unit under identical conditions at baseline, 2 weeks, 4 weeks and 6 weeks.

2.2 Composition of the Commercially Available Gel Formulation

Hi-Ora-GA Gel 15ml preparation: Each gram of HiOra-GA gel contains: Oil. Jatiphala (*Myristica fragrans*) 1.5mg, Arjuna (*Terminalia Arjuna*) 8.0mg, Asana (*Pterocarpus marsupium*) 12.0mg and Triphala 20.0mg.

Herbashine Herbal Gum Paint 15ml preparation: Each ml contains oils of *Mentha Spicata* 2.5% v/v, Cinnamomum Camphora 1% v/v, *Syzygium Aromaticum* 2.5% v/v, *Trachyspermum Ammi* 2% v/v, *Melia Azedarach* 2% v/v, Glycerin Base q.s.

2.3 Statistical Analysis

Intra group and inter group comparisons were made by one way Analysis of variance (ANOVA). Null hypothesis was considered if there is no significant difference in the mean index value of the three groups i.e. $\mu_1 = \mu_2 = \mu_3$. Alternate hypothesis was considered if there is a significant difference in the mean index value of the three groups i.e. $\mu_1 \neq \mu_2 \neq \mu_3$. Level of significance was considered at $\alpha = 0.05$. Decision criterion was to reject the null hypothesis if the p-value is less than 0.05. Otherwise we accept the null hypothesis. If there is a significant difference between the groups, we carry out multiple comparisons (post-hoc test) using Bonferroni test.

3. Results and Discussion

3.1 Results

Plaque index and gingival index scores of all groups at different follow-ups (Table 1). In the intergroup comparison at baseline there was no statistically significant difference between Groups I, II and III with respect to PI and GI scores. There was a gradual decrease in the PI and GI scores by the 2nd week, 4th week and 6th week time interval, respectively, in all three groups (Table 2, Table 3 Graph 1-8). A statistically significant reduction in PI and GI scores was observed for Groups I, II and III at all-time intervals. Group III showed a significant reduction in GI scores at all-time intervals and PI scores at 2, 4 and 6 weeks as compared to Groups I, II but not between 4 and 6 weeks. (Tables 2 and Table 3).

Intergroup comparison of PI value was found to be statistically significant between Control and Herbashine Gel groups ($P < 0.001$), Control and Hi-ora Gel groups ($P < 0.001$) as well as between Herbashine Gel and Hi-ora Gel groups ($P < 0.001$) at baseline, 2 weeks, 4 weeks and 6 weeks (Table 4 and Table 5).

3.2 Tables

Table 1: Plaque index and gingival index scores of all groups at different follow-ups

Groups	Gingival index scores at baseline and different follow-ups				Plaque scores at baseline and different follow-ups			
	Baseline	2 weeks	4 weeks	6 weeks	Baseline	2 weeks	4 weeks	6 weeks
Group1	2.198±0.148	1.549±0.138	1.495±0.096	1.506±0.089	2.215±0.183	1.791±0.152	1.607±0.114	1.579±0.120
Group2	2.128 ±0.093	1.580±0.072	1.263±0.124	0.733±0.081	2.176±0.115	1.461±0.097	0.993±0.095	0.677±0.086
Group3	2.194±0.117.	1.547±0.081	0.954±0.100	0.568±0.049	2.185±0.074	1.499±0.165	0.755±0.111	0.442±0.053

*p < 0.001

Table 2: Inter-group comparison of reduction in gingival index scores

	Groups	Gingival index (Mean ± SD % Reduction)			
		Baseline	2 weeks	4 weeks	6 weeks
F-value		2.106	0.689	127.965	895.039
P-value		0.131	0.506	0.001*	0.001*
	Group 1& Group 2	0.070 ±0.216	-0.032±0.988	0.001*	0.001*
	Group 1& Group 3	0.005 ±1.000	0.002±1.000	0.001*	0.001*
	Group2& Group3	.0066±0.275	0.002±1.000	0.001*	0.001*

*p < 0.001

Table 3: Inter-group comparison of reduction in plaque index scores

	Groups	Plaque scores (Mean ± SD % Reduction)			
		Baseline	2 weeks	4 weeks	6 weeks
F-value		0.480	32.892	337.810	880.184
P-value		0.621	0.001*	0.001*	0.001*
	Group 1& Group 2	0.039±1.000	0.001*	0.001*	0.001*
	Group 1& Group 3	0.030±1.000	0.001*	0.001*	0.001*
	Group2& Group3	0.009±1.000	0.001*	0.001*	0.001*

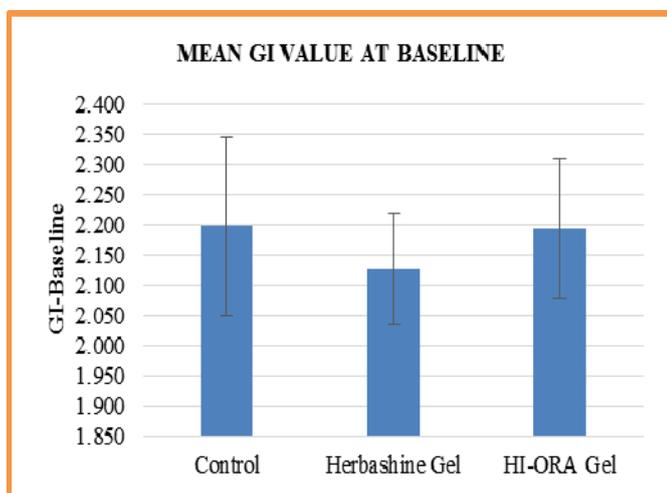
Table 4: Intra-group comparison of reduction of gingival score

Groups	Gingival index (Mean ± SD % Reduction)			
	Baseline	2 weeks	4 weeks	6 weeks
Group 1	2.198±0.148 0.580	1.549±0.138 0.770	1.495±0.096 0.330	1.506±0.089 0.400
Group 2	2.128±0.093 0.340	1.580±0.072 0.280	1.263±0.124 0.450	0.733±0.081 0.300
Group 3	2.194±0.117 0.350	1.547±0.081 0.320	0.954±0.100 0.300	0.568±0.049 0.140

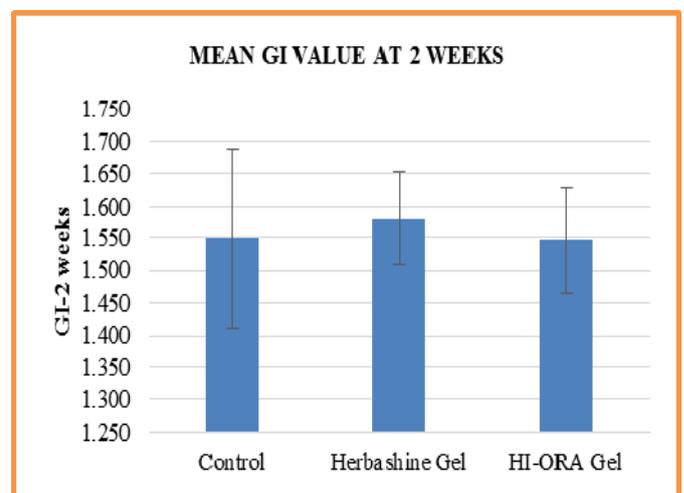
Table 5: Intra-group comparison of reduction of plaque score

Groups	Plaque scores (Mean ± SD % Reduction)			
	Baseline	2 weeks	4 weeks	6 weeks
Group 1	2.215±0.183 0.590	1.791±0.152 0.630	1.607±0.114 0.400	1.579±0.120 0.420
Group 2	2.176±0.115 0.300	1.461±0.097 0.230	0.993±0.095 0.320	0.677±0.086 0.340
Group 3	2.185±0.074 0.360	1.499±0.165 0.570	0.755±0.111 0.370	0.442±0.053 0.190

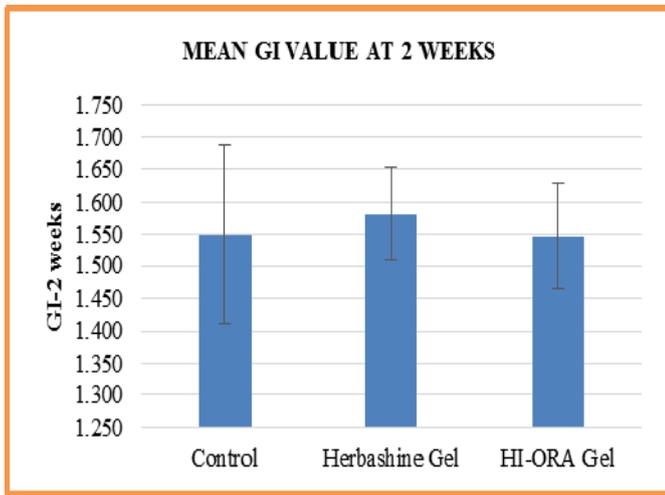
3.3 Graphs



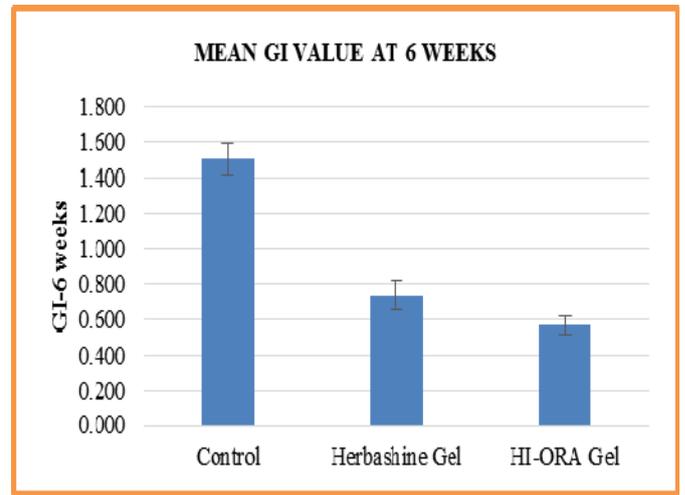
Graph 1



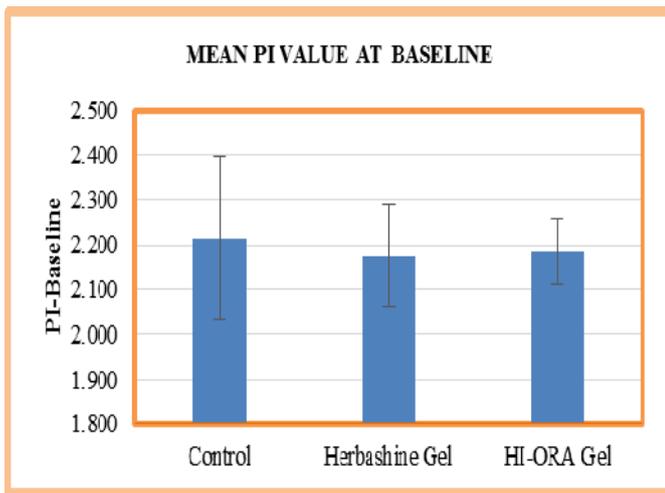
Graph 2



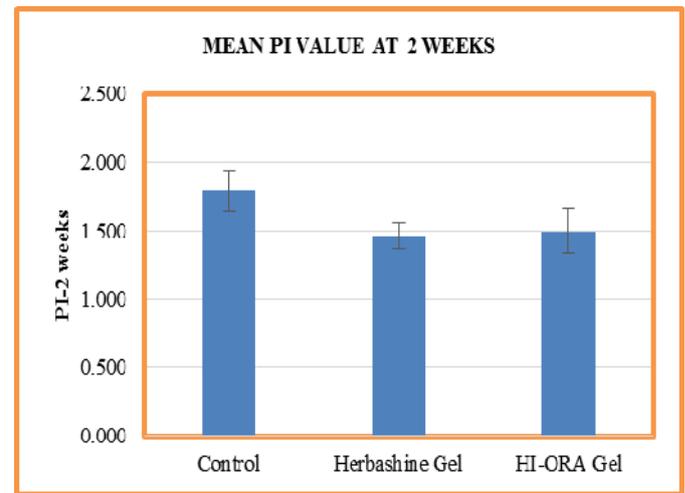
Graph 3



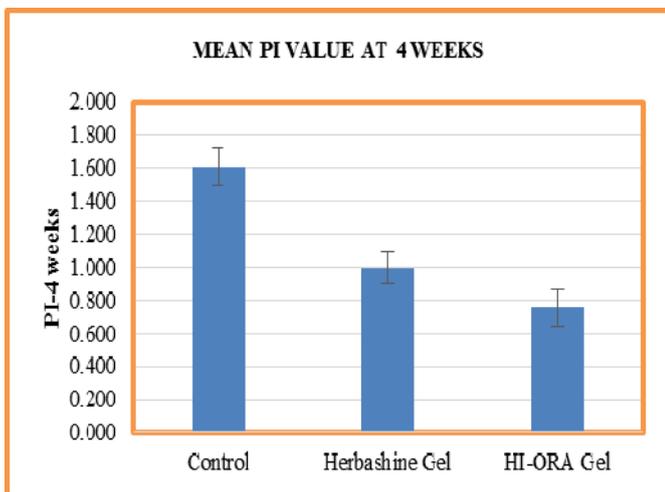
Graph 4



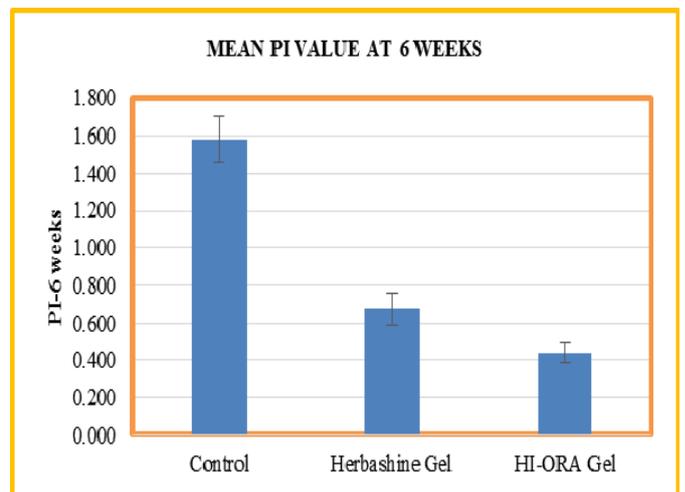
Graph 5



Graph 6



Graph 7



Graph 8

3.4 Discussion

Plaque is the main agent responsible for the breakdown of periodontal tissues leading to periodontal disease. The removal of this plaque regularly is of paramount importance in the prevention of periodontal disease. The inability of the adult population to perform adequate mechanical tooth cleaning has stimulated the search for chemotherapeutic agents that has been used to improve plaque control and prevent gingivitis. So various means have been established and search is going on to reduce the plaque and gingival inflammation. Herbal products

are one group of agents which has been used extensively in reducing the Plaque. Phytotherapeutic products have been investigated with these purposes and have shown satisfactory results. Hence the evaluation of efficacy of Triphala gel (HiOra-GA[®] gum gel (Himalaya herbal health care)) formulation and cinnamomum gel (Herbashine Herbal Gum Paint[®] (Uniroyal biotech)) formulation on gingivitis and its use in the treatment of gingivitis was carried out.

In the present study, a significant reduction in PI and GI scores at 2weeks, 4 week and 6 week time intervals was observed

with the use of both gels. The positive clinical effects of both gel can be attributed to their various ingredients [14-22]. the reduction in plaque and gingivitis scores in Group 1 (control group) can be attributed to the effect from the scaling procedure in the clinical trial scaling was performed at the baseline so that all subjects had similar minimal levels of plaque. The inhibitory effect of Herbashine Herbal Gum Paint[®] can be attributed to active constituents like Cinnamomum camphora, Mentha Spicata, ajwain and clove. Similarly the inhibitory effect of HiOra-GA[®] gum gel can be attributed to active constituents like Jatiphala, Arjuna, Triphala. The properties of various constituents of the gel can give rise to their anti-plaque and anti-gingivitis effects. The use of Triphala in dentistry for treatment of gingivitis has been advocated from many centuries. Study conducted by Prakash and Shelke have shown the uses of Triphala in dentistry in reducing plaque and controlling gingivitis [23]. Kaur GJ has shown antibacterial and antifungal activities of Ajwain [24]. Bhowmik D *et al.* has shown clove to reduce gingivitis because of germicidal, antibacterial and antifungal properties [25]. A clinical study by Pawar *et al.* has revealed that herbal dentifrice containing cinnamomum camphora and menthol has reduced plaque in gingivitis patients [26].

Although both the gel have been found to be effective in improving gingival status and resulted in significant improvement in clinical parameters, HiOra-GA[®] gum gel was found to be more effective than Herbashine Herbal Gum Paint[®].

4. Conclusion

The widespread occurrence of gingivitis provides the rationale for supplementing toothpastes with anti-gingivitis agents that augment mechanical plaque removal, Hi-Ora-GA[®] gum gel showed significant clinical improvement in gingival and plaque index scores as compared to Herbashine Herbal Gum Paint[®]. Thus, this study suggests that both the formulation may be useful for chemical plaque control in subjects with gingivitis and Hi-Ora-GA[®] is more effective in treating gingivitis. Further long-term longitudinal studies are required to confirm the findings of this study.

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